IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL CORPORATION, Plaintiff, v. NYCOMED US INC., Defendant.	C. A. No. 10-1099-SLR

OPENING BRIEF IN SUPPORT OF DEFENDANT
NYCOMED US INC.'S MOTION TO DISMISS THE COMPLAINT

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I. INTRODUCTION

In its Complaint, Medicis Pharmaceutical Corporation ("Medicis") accuses Nycomed US Inc. ("Nycomed") of infringing U.S. Patent No. 7,794,738 ("the '738 patent"), advancing two theories of liability. First, Medicis contends that the filing of Nycomed's Abbreviated New Drug Application ("ANDA") for a generic fluocinonide cream infringes the '738 patent under 35 U.S.C. § 271(e)(2)(A). Second, Medicis seeks declaratory judgment that, if and when the Food and Drug Administration ("FDA") approves Nycomed's product and Nycomed engages in the commercial manufacture, use, sale or offer for sale of the product, Nycomed will infringe the '738 patent under 35 U.S.C. § 271(a), (b), and/or (c). The first theory of liability fails to state a claim on which relief can be granted. The second does not present a justiciable controversy. Accordingly, Medicis' Complaint should be dismissed.

Filing an ANDA with a so-called "Paragraph IV certification" gives rise to a claim of constructive infringement under section 271(e)(2) as to each patent against which a Paragraph IV certification was filed. Here, Nycomed has not filed a Paragraph IV against the '738 patent, which was only recently issued and listed in the Orange Book, and did not exist when Nycomed filed its ANDA. Because Nycomed has not made a Paragraph IV certification with respect to the '738 patent, Medicis cannot state a claim for patent infringement under section 271(e)(2).

As to Medicis' declaratory judgment claim, the Court lacks subject matter jurisdiction to adjudicate a claim seeking a declaration that Nycomed's generic product will, at some indeterminate point in the future, if approved, infringe the '738 patent. Nycomed is not currently engaged in the commercial manufacture or sale of its proposed generic product, nor has the FDA approved the marketing or selling any such product. Given that the timing of FDA approval and subsequent commercialization by Nycomed are entirely speculative at best, Medicis' claim fails to present a live "case or controversy" under the Declaratory Judgment Act and Article III of the

U.S. Constitution. Moreover, allowing this claim to proceed would undermine the structure of the Hatch-Waxman Act, as established by Congress.

Accordingly, Nycomed respectfully requests that the Court dismiss Medicis' complaint in its entirety pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(b)(1).[1]

II. BACKGROUND

A. THE DRUG APPROVAL PROCESS UNDER THE HATCH-WAXMAN ACT

In the United States, all new drugs must be approved by the FDA before they are distributed in interstate commerce. 21 U.S.C. § 355(a). To obtain approval for a new drug, applicants must file with the FDA a New Drug Application ("NDA") that includes, *inter alia*, clinical data demonstrating that the drug is safe and effective for use. *Id.* § 355(b)(1)(A), (b)(1)(F). The NDA must also contain the patent number and expiration date of any patent that has claims purporting to cover either the drug or a method of using the drug. *Id.* § 355(b)(1). The FDA publishes the names of approved drugs and their associated patent information in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, more commonly referred to as the "Orange Book."

Applicants seeking to market a generic version of a drug already approved by the FDA may file an ANDA, which permits applicants to rely on the previously submitted safety and efficacy information, as long as the generic drug is shown to be "bioequivalent" to the approved

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[1] Contemporaneous with the filing of this motion, Nycomed is filing a motion to transfer venue to the Southern District of New York. *See* Def. Nycomed US Inc.'s Mot. To Transfer Venue to the S.D.N.Y. As set forth in that motion, Nycomed believes that Medicis prematurely filed the instant lawsuit in an attempt to generate arguments in opposition to Nycomed's motion to transfer venue in another action in this district, *Medicis Pharm. Corp. v. Nycomed US Inc. et al.*, Civ. No. 10-419-SLR.

drug. *Id.* § 355(b)(2), (j). For each patent listed in the Orange Book that claims to cover the listed drug for which approval is sought, the ANDA must include one of four certifications.

These certifications are commonly known as Paragraph I, II, III, and IV certifications. Paragraph I and II certifications permit immediate approval of the ANDA because there are no patents listed in the Orange Book, or because all of the listed patents have expired. *Id.* § 355(j)(5)(B)(i). A Paragraph III certification states that the applicant does not seek approval until the expiration of the listed patent. Most relevantly, for purposes of this case, a Paragraph IV certification is a statement that the applicant seeks FDA approval prior to the expiration of the listed patent because it believes the patent to be invalid and/or not infringed. A party that files a Paragraph IV certification must give notice to the patentee and the NDA holder and provide a detailed basis for its belief that the patent is invalid and/or not infringed. 21 U.S.C. § 355(j)(2)(B)(i). Such a notice is, appropriately enough, commonly known as a "Paragraph IV Notice Letter."

It is this certification and the required notice to the patent owner and NDA holder that give rise to a statutory cause of action under 35 U.S.C. § 271(e), which provides in relevant part:

> (2) It shall be an act of infringement to submit--
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . .

Submitting an ANDA containing a Paragraph IV certification constitutes "a highly artificial act of infringement" under section 271(e)(2)(A) necessary to trigger an early adjudication of the patent holder's rights under the patent. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

B. NYCOMED'S ANDA AND THE ENSUING LITIGATION

As alleged in the complaint, Medicis is the holder of NDA No. 21-758, approved by the FDA for the marketing and sale of the brand name drug Vanos®, which is indicated for the treatment of psoriasis, dermatitis, and corticosteroid responsive dermatoses. (Compl. ¶¶ 11-12.) On April 7, 2010, Nycomed notified Medicis of the filing of Abbreviated New Drug Application No. 20-735 to obtain approval to market a generic version of Vanos®. (*Id.* ¶¶ 13-14.) At the time of the filing of the ANDA, U.S. Patent Nos. 6,765,001 ("the '001 patent") or 7,220,424 ("the '424 patent") were the only patents Medicis had listed in the Orange Book entry for Vanos®. (*Id.* ¶¶ 8-9.) Nycomed's ANDA includes a Paragraph IV certification that the commercial manufacture and sale of its proposed generic product will not infringe the '001 or '424 patents. (*Id.*) On May 19, 2010, Medicis filed identical actions against Nycomed in this District and in the Southern District of New York, alleging infringement of the '001 and '424 patents, as well as a third related patent, U.S. Patent No. 7,217,422 ("the '422 patent"), which is not listed in the Orange Book.

As alleged in Medicis' complaint in this action, on September 14, 2010, the Patent Office issued the '738 patent. Medicis amended its Orange Book entry for Vanos® to include the '738 patent and subsequently brought this action, despite the fact that Nycomed has not filed a Paragraph IV certification with regard to the '738 patent, and has not provided any notice to Medicis of such a certification.

III. ARGUMENT

A. MEDICIS HAS NOT ALLEGED A COGNIZABLE "ACT OF INFRINGEMENT" UNDER 35 U.S.C. § 271(e)(2).

As a matter of law, Medicis cannot allege an "act of infringement" under 35 U.S.C. § 271(e)(2) because it is undisputed that Nycomed's ANDA does not include a Paragraph IV

certification with respect to the '738 patent. (Compl. ¶¶ 13-15.) Accordingly, Medicis' section 271(e)(2) claim should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6).

The Supreme Court has described section 271(e)(2) as creating a "highly artificial act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification." *Eli Lilly & Co.*, 496 U.S. at 678. In *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130 (Fed. Cir. 1995), the Federal Circuit described the Hatch-Waxman Act as giving "a drug patent owner the right to bring an action for infringement upon the filing of a paragraph IV certification." *Id.* at 1135. Over the years, the Federal Circuit has reiterated this view of the statute. *See, e.g., Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1362 (Fed. Cir. 2010) ("the Act makes a Paragraph IV certification into an act of patent infringement"); *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1323 n.4 (Fed. Cir. 2009) ("A Paragraph IV certification is defined as an act of infringement for litigation purposes."); *Astrazeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 769 (Fed. Cir. 2009) ("Paragraph IV certifications are, by statute, an act of technical patent infringement designed to permit litigation of patent issues for products subject to federal regulatory approval. 35 U.S.C. § 271(e)(2)(A)."); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1078 (Fed. Cir. 2008) ("Such 'paragraph IV certification' is defined as an act of infringement for litigation purposes."). Without that technical act of infringement, Medicis simply has no cognizable claim as to the '738 patent.

In *Eisai Co. v. Mutual Pharmaceutical Co.*, No. 06-3613, 2007 WL 4556958 (D.N.J. Dec. 20, 2007), the district court held that a Paragraph IV certification was a pre-requisite to stating a claim under Section 271(e)(2). There, the generic manufacturer had made Paragraph IV certifications against four of the five patents listed for the branded drug, but not against the late-

listed '841 patent. *Id.* at *6. Eisai, the branded drug manufacturer, brought suit under 35 U.S.C. § 271(e)(2) on the theory that the mere filing of the ANDA infringed the '841 patent. *Id.* at *7. After reviewing the language of the statute, the structure of the Hatch-Waxman Act, and the case law interpreting its provisions, the court dismissed the plaintiff's section 271(e)(2) claim directed to the '841 patent because the ANDA did not contain a Paragraph IV certification as to that patent. The court reasoned that the Supreme Court and the Federal Circuit had "conditioned the act of infringement defined by § 271(e)(2) on the filing of a Paragraph IV certification, and not just an ANDA with any type of certification (or no certification)."[2] *Id.* at *11.

In this case, the ANDA in question includes Paragraph IV certifications for patents other than the patent-in-suit, but not the patent-in-suit itself. Those certifications are the subject of a different lawsuit. The act of infringement required by the statute to state a claim for infringement of the '738 patent has not occurred, and unless and until it does, there is no cause of action under section 271(e)(2).

Medicis cannot rely on the district court cases holding that the filing of an ANDA that should include, but does not include, a Paragraph IV Certification nevertheless constitutes an "act of infringement" which confers jurisdiction under section 271(e)(2)(A). *See, e.g., Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 09-2445, 2010 WL 1372437, at *11-13 (D.N.J. March 31, 2010). Those cases narrowly hold that ANDA filers should not be permitted to avoid an infringement through "artful" drafting of the ANDA. *Id.* In this case, however, Nycomed's

[2] Although the court's opinion notes that Mutual had no obligation to file a Paragraph IV certification because the '841 patent was untimely listed in the Orange Book, the court did not rely on that fact in concluding that "[i[n the face of the Federal Circuit's direct statements, which rely in part on the Supreme Court's comments in *Eli Lilly*, . . . this Court holds that to establish an act of infringement pursuant to § 271(e)(2), the ANDA must contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question." *Id.* at *12.

ANDA included Paragraph IV certifications for the two patents that were actually listed in the Orange Book at the time the ANDA was filed. There is nothing in Medicis' complaint, nor could there be, to suggest either that Nycomed's ANDA as originally filed was "artfully" drafted to avoid an infringement suit or that the FDA will require Nycomed to amend its ANDA to include a Paragraph IV certification with respect to the '738 patent.

The Court should therefore dismiss Medicis' section 271(e)(2) claim because Nycomed's ANDA contains no Paragraph IV certification regarding the '738 patent, and therefore Medicis has no legal basis to allege patent infringement by Nycomed.

B. THERE IS NO "ACTUAL CONTROVERSY" AND THUS NO SUBJECT MATTER JURISDICTION OVER THE CLAIM FOR A DECLARATORY JUDGMENT OF INFRINGEMENT UNDER 35 U.S.C. § 271(a)-(c).

Medicis' additional claim for relief under 35 USC 271(a)-(c) lacks the immediacy and ripeness required of an "actual controversy" under the Declaratory Judgment Act. The Court should, therefore, also dismiss that claim for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1).

For sure, a patentee is permitted to seek a declaration that a person will infringe a patent in the future by making, using and/or selling a patented invention. *See Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 763 (Fed. Cir. 1990); 35 U.S.C. § 271(a)-(c). As with any declaratory judgment plaintiff, however, the patentee must prove the existence of a "case of actual controversy" by a preponderance of the evidence. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 887 (Fed. Cir. 1992). The phrase "case of actual controversy" in the Declaratory Judgment Act "refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). Consequently, the analysis of whether "a case of actual controversy" exists is essentially an analysis of whether standing under Article III exists. *See generally id.*; *see also, e.g.*, *SanDisk Corp. v. STMicroelectronics, Inc.*,

480 F.3d 1372, 1381 (Fed. Cir. 2007). As such, an actual controversy exists where "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune,* 549 U.S. at 127 (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

Nycomed's future commercial sale of the proposed ANDA product is entirely contingent on FDA approval as well as the outcome of the already pending litigation between the parties. There is nothing in the complaint to suggest that FDA approval is imminent and it is "impossible to know when the FDA might make such a determination." *Intermedics, Inc. v. Ventritex Co.*, No. 92-1067, 1993 WL 87405, at *4 (Fed. Cir. Feb. 22, 1993). In fact, the FDA's approval of Nycomed's ANDA was automatically stayed for 30 months by the filing of Medicis' first actions against Nycomed (unless there is an earlier judicial determination that the two patents at issue in that litigation are invalid and/or not infringed). *See* 21 U.S.C. § 355(j)(5)(B)(iii).

The complaint also lacks any allegation that Nycomed has made or is planning to make preparations for the launch of its proposed ANDA product. Indeed, as with any future business decision, there are any number of scenarios under which Nycomed may not engage in the commercial manufacture and sale of the accused product, even if the FDA were to approve its ANDA, including, *inter alia*, a change in market conditions, business strategy, the availability of raw material or manufacturing equipment, and/or new and improved competing drugs. Medicis simply cannot, therefore, establish the required "immediacy and reality" to state an "actual controversy" sufficient to confer declaratory judgment jurisdiction over its §§ 271(a), (b), and/or (c) claims. *See PSA, LLC v. Gonzales*, 461 F. Supp. 2d 351, 356 (E.D. Pa. 2006) ("The surest sign that a case lacks sufficient adversity to be ripe for decision is when the dispute between the

parties is contingent on some future event."); *Eisai*, 2007 WL 4556958, at *18 ("At least until the ANDA is approved, ... the controversy is not sufficiently immediate."); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 938 (N.D. Ill. 1995) ("[T]he fact that Defendant requested FDA approval of its generic version [] does not mean that Defendant will not change its course of actions and decide not to market the drug.").

Courts routinely decline declaratory judgment jurisdiction when, as here, the alleged future infringement is contingent on FDA approval and the defendant has not yet engaged in any sales, marketing, and/or promotional activity. *See, e.g.*, *Intermedics*, 1993 WL 87405, at *4 (affirming district court's determination not to exercise its declaratory judgment jurisdiction for failure to meet the actual controversy requirement in large part because FDA "had yet to grant premarket approval ...."); *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992) (affirming district court's finding that a defibrillator component manufacturer's claim for future patent infringement lacked a sufficient allegation of immediacy to support a declaratory judgment action, in part because the potentially infringing defibrillator had not been approved by FDA); *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, C.A. No. 05-590, 2006 WL 2375035 (D. Del. Aug. 16, 2006) (dismissing declaratory judgment claim where FDA had not approved defendant's product and defendant had not engaged in any sales and/or marketing activity); *Eisai*, 2007 WL 4556958, at *18 ("Even accepting Eisai's allegations regarding Mutual's representations as true, Eisai has alleged only that Mutual might hit the market upon FDA approval of its ANDA. However, only § 271(e)(2) allows Eisai to seek judicial resolution of its patent claims prior to ANDA approval.").

C. THE COURT SHOULD DECLINE TO EXERCISE ITS DISCRETIONARY JURISDICTION OVER THE DECLARATORY JUDGMENT CLAIM.

The Declaratory Judgment Act provides that a court "*may* declare the rights and other legal relations of any interested party," 28 U.S.C. § 2201(a) (emphasis added), not that it *must* do so. In *MedImmune*, the Supreme Court noted that the Act has long been understood "to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants." 549 U.S. at 136 (citing *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995)). The Court found it "consistent with the statute . . . to vest district courts with discretion in the first instance, because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp." *Id.* Thus, even if this Court were to find that this case presented a live controversy for purposes of declaratory judgment jurisdiction (which it should not), the Court should in its discretion decline to exercise that jurisdiction. *See, e.g.*, *Telectronics*, 982 F.2d at 1527-28; *Eisai*, 2007 WL 4556958, at *21.

As set forth in Nycomed's contemporaneously-filed motion to transfer, Nycomed believes that Medicis prematurely filed the instant lawsuit in an attempt to generate arguments in opposition to Nycomed's motion to transfer venue in another action in this district, *Medicis Pharm. Corp. v. Nycomed US Inc. et al.*, C.A. No. 10-419-SLR. Because this suit appears to have been preemptively filed in an effort to gain a perceived tactical advantage in the parallel action pending in this district, the Court would be well within its authority to decline declaratory judgment jurisdiction over the matter.

Moreover, exercising declaratory judgment jurisdiction over Medicis' claim would be tantamount to circumventing Congress's recognized intention, as expressed in the Hatch-Waxman Act, that infringement suits in this context must be predicated on an ANDA containing a Paragraph IV certification with respect to the patent-in-suit. *See Zenith Labs.*, 934 F. Supp. at

938 ("[T]his Court refuses to exercise jurisdiction over Plaintiff's declaratory judgment claim because it would undermine Congress' policy in enacting the 1984 Act . . . ."); *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1290 (N.D. Cal. 1991) ("It makes little sense, and thus we assume would be inconsistent with Congress' intent, to protect companies like [defendant] from suit for actual patent infringement but leave them fully exposed to declaratory relief actions whose gravamen and burdens are much the same."). Moreover, the prospect of FDA approval and commercialization are too remote in time to merit judicial intervention now. *Intermedics, Inc.*, No. 92-1067, 1993 WL 87405, at *4 (affirming district court's refusal to exercise declaratory judgment jurisdiction on the ground that "the FDA had yet to grant premarket approval of the device" and "it was impossible to know when the FDA might make such a determination"). Medicis will have the opportunity to bring suit against Nycomed in the future, should those contingencies come to pass. Thus, even if Medicis' allegation of future infringement were to rise to the level of an "actual controversy," the Court should exercise its discretion to decline declaratory judgment jurisdiction over this matter.

IV. CONCLUSION

For the foregoing reasons, Nycomed respectfully requests that the Court grant its motion to dismiss the complaint in its entirety.

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DATED: February 15, 2011

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on February 15, 2011, I caused to be filed the foregoing document with the Clerk of Court using CM/ECF, which will send notification of such filing(s) to counsel of record, and have sent true and correct copies to the following as indicated:

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